8EHQ - 0898-14248

FLEXSYS

18 August, 1998

Document Processing Center
Attn: TSCA 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460-0001

Contains No CBI

RE: Notification of new information of substantial risk under TSCA Section 8(e)

Dear Sir or Madam,

As stipulated in Section 8(e) of the Toxic Substances Control Act, Flexsys America L.P. is submitting the following summary of preliminary results from epidemiological research being conducted by Dr. Tom Sorahan, Reader in Occupational Epidemiology at the University of Birmingham in the United Kingdom.

The chemical involved is 2-mercaptobenzothiazole [CAS# 149-30-4], commonly known as MBT. These most recent findings are results from an extension of earlier occupational epidemiological studies which examined mortality rates for exposed chemical plant workers at MBT/MBT derivative manufacturing facilities in North Wales in the UK and in Nitro, West Virginia.

The original studies consisted of a group of 2160 male production workers employed at the North Wales plant and 1059 male production workers employed at the US facility who worked a minimum of six months between the years 1955-1986 and were potentially exposed to MBT and MBT derivatives. A statistically significant increase in bladder cancer was identified for US workers who were co-exposed to p-Aminobiphenyl [CAS #92-67-1], a recognized potent bladder carcinogen. ***[1] [2]*** A slightly elevated but statistically insignificant rate was seen in the North Wales subjects, but those workers were co-exposed to beta-Naphthylamine [CAS #135-88-6], ortho-Toluidine [CAS #95-53-4] and Aniline [CAS # 62-53-3], all of which are either known or suspected bladder carcinogens. ***[3] [4] [5] [6]***

Both studies were continued to follow the two worker populations for an additional six years. The update of the Nitro study, completed in 1996, showed no bladder cancers in

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The North Wales update -- the subject of this notification – was recently completed by the University of Birmingham. This update examined subgroups of workers classified as exposed to MBT, employed in the Phenyl-b-naphthylamine (PBN) department, employed in the ortho-Toluidine department, and employed in the Aniline department. Significant excesses of bladder cancer were identified for those employees with MBT, PBN and o-Toluidine exposure. In addition, workers presumably exposed to MBT exhibited a small but statistically significant increase in the number of cancers of the large intestine.

Significantly, there was substantial overlap in the membership of these exposure groups, confounding an analysis of causality. Many assumptions were also made regarding the cumulative duration of MBT exposure and estimated concentration (dose) present in the MBT manufacturing and handling areas of the plant. The elevated death rates are seen in workers hired between 1930-1954 when PBN and o-Toluidine were still in use at the North Wales plant. It is a plausible hypothesis that co-exposure to all three substances, rather than exposure to MBT alone, accounts for the observed increase in bladder cancer rates. This hypothesis is further reinforced by the apparent lack of a dose-response relationship between exposure to MBT and elevated risk of bladder cancer.

MBT has been the subject of numerous studies conducted under TSCA Section 4 Test Rules, by the National Toxicology Program (NTP TR 332), and through the Chemical Manufacturers Association. None of these studies has indicated any association between the exposure to MBT and the development of cancers of the bladder or large intestine.

The University of Birmingham continuation study has not yet been issued in the form of a final report, nor have the results been peer-reviewed or published. Flexsys America L.P. will submit this final report to the US EPA as a follow-up to this notification when it becomes available to us. Until that time, should you have any questions regarding this notification, please do not hesitate to contact me at (330) 668-8281 or by FAX at (330) 668-8345.

Sincerely,

Sharen B. Breyer
ES&H Specialist / Product Safety Manager
Flexsys America L.P.

[1] Strauss ME, Barrick ED, Bannister RM. "Mortality Experience of Employees Exposed to 2-Mercaptobenzothiazole at a Chemical Plant in Nitro, WV." *Brit J Indust Medicine 1993;50:888-893*

[2] DHHS (NIOSH) Publication No. 92-100 4-Aminobiphenyl (bladder cancer)

[3] Sorahan T, Pope D. "Mortality Study of Workers Employed at a Plant Manufacturing Chemicals for the Rubber Industry, 1955-1986" *Brit J Indust Medicine 1993;50:998-1002*

[4] DHHS (NIOSH) Publication No. 92-100 N-Phenyl-beta-naphthylamine (bladder cancer)

[5] DHHS (NIOSH) Publication No. 92-100 o-Toluidine (tumors of liver, bladder, mammary glands)

[6] DHHS (NIOSH) Publication No. 92-100 Aniline and homologs (potential for cancer)